Estimated Annual Reporting Burden					
Type of Response[1]	No. of Respondents[2]	Annual Frequency per Response[3]	Total Annual Responses[4]	Hours per Response	Total Hours
NDA[5]	162	22.9	3,715	40	148,600
ANDA[6] and AADA[7]	350	18.6	6,517	40	260,680
ELA[8] and PLA[9]	391	4.9	1,905	40	76,200
Total Burden Hours					485,480

There are no capital costs or operating and maintenance costs associated with this collection.
[1] Includes original applications and their amendments and supplemental applications
[2] Number of sponsors submitting applications during fiscal year (FY) 95
[3] Average number of applications submitted per sponsor
[4] Total applications submitted during FY 95
[5] New Drug Application (includes applications for new antibiotic drugs)
[6] Abbreviated New Drug Application
[7] Abbreviated Antibiotic Drug Application
[8] Establishment License Application
[9] Product License Application

In FY 95, CDER received a total of 10,232 submissions and CBER received 1,905 submissions that would require use of this application form. FDA estimates that 40 hours would be needed for an industry regulatory affairs specialist to fill out the harmonized form, collate the documentation, and submit the application to CDER or CBER.

Dated: March 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6360 Filed 3–12–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1996. FDA has announced the availability of previous lists, which are brought up-to-date monthly, identifying the drugs and biologicals granted orphan-drug designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Peter L. Vaccari, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0983.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologicals. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologicals, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses.

The list that is the subject of this notice consists of designated orphan drugs and biologicals through December 31, 1996, and, therefore, brings the April 22, 1996 (61 FR 17708) publication up to date. This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify the docket number found in brackets in the heading of this document.

The orphan-drug designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing an orphan drug or biological must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for these products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: March 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6357 Filed 3–12–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0283]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information regarding Regulations under the Federal Import Milk Act, has been approved by the Office of Management and Budget (OMB), under the Paperwork Reduction